IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *ex rel.* DAVID KESTER, et al., Plaintiffs, v. NOVARTIS PHARMACEUTICALS CORPORATION, ACCREDO HEALTH GROUP, INC, BIOSCRIP CORPORATION, CURASCRIPT, INC., CVS CAREMARK CORPORATION, Defendants.	No. 1-11-cv-08196-CM

RELATOR DAVID M. KESTER'S MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANT NOVARTIS'S MOTION TO DISMISS

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Relator David M. Kester respectfully submits this memorandum of law in opposition to the motion to dismiss filed by defendant Novartis Pharmaceuticals Corporation ("Novartis") on June 13, 2014 (Dkt. No. 207). For the reasons stated herein, Novartis's motion to dismiss Kester's Second Amended Complaint ("Complaint") should be denied.

PRELIMINARY STATEMENT

Novartis argues that to allege a False Claims Act ("FCA") violation based on violations of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), the Government and Kester must plead that the alleged kickbacks caused patients to receive medication "because of the corrupting influence of a pharmacy over a doctor or patient." Novartis Kester Br. at 3. By this, Novartis means that plaintiffs must show for each claim that the drugs ordered were "not necessary or [were] clinically inappropriate," Novartis Gov't Br. at 2, and that the kickback actually influenced the physician's or patient's decision to prescribe or refill the prescriptions at issue, *id.* There is no basis for Novartis's proposed causation requirements in the AKS or FCA, and adopting these proposals would, as the Court itself has observed, "significantly restrict the definition of legally 'false' claims in the kickback context." *United States ex rel. Kester v. Novartis Pharms. Corp.*, ___ F. Supp. 2d ___, 2014 WL 2324465, at *25 (S.D.N.Y. May 29, 2014) (*Novartis I*).

Novartis misconceives what is required to establish a violation of the FCA based on a kickback arrangement. While Novartis argues that a kickback must be shown to have actually influenced a physician's or patient's decision to order a drug, and further that the drug was not otherwise clinically appropriate for the patient, the Court properly noted in *Novartis I* that:

> [T]he AKS does not require a kickback scheme to succeed in generating new business (*i.e.,* new patient prescriptions) in order for a violation to have occurred . . . . A pharmaceutical company violates the AKS if it "offers" a pharmacy a kickback "to induce" the pharmacy to "recommend[ ] purchasing"

> the company's drugs. . . . And the pharmacy violates the AKS if it "receives" a kickback "in return for . . . recommending purchasing" those drugs. . . . The pharmacy violates the AKS even if it only "solicits" a kickback in exchange for recommending drugs covered by government programs. . . . Thus, it is the kickback arrangement itself that constitutes the AKS violation, not the success of the arrangement. The illegal recommendations in question do not have to actually convince someone to purchase the drugs who would not have otherwise done so.

Id. at *19 (emphasis added). The only causal link that is required when an FCA claim is based on a kickback violation is proof that kickbacks were paid in connection with the sale of each drug that was included in a claim for reimbursement from one of the government payors at issue, and that requirement is indisputably satisfied in this case. *See, e.g.*, *United States v. Rogan*, 517 F.3d 449, 453 (7th Cir. 2008) ("Nor do we think it important that most of the patients for which claims were submitted received some medical care—perhaps all the care reflected in the claim forms. . . . When the conditions [of compliance with the AKS] are not satisfied, nothing is due. Thus the entire amount that [the hospital] received on these 1,812 claims must be paid back.").

Novartis relies on a March 23, 2010 amendment to the AKS to support its causation argument, but as discussed below, neither the text nor legislative history of that amendment supports Novartis's reading. In fact, the purpose of that amendment was to strengthen the enforcement of the healthcare laws, not curtail it by requiring an unprecedented inquiry into the thought-processes of physicians and patients in the way Novartis proposes. Notably, even Novartis concedes that this amendment "did not add a new causation requirement for an FCA action premised on a kickback claim." Novartis Gov't Br. at 9. Novartis's novel causation requirement should be rejected.

Novartis also contends that Kester's conspiracy claims should be dismissed. Improperly rearguing a point that this Court already decided, Novartis argues that because the Court has held that Kester's complaint does not plead false claims with requisite particularity under Rule 9(b)

for the drugs Gleevec, Tasigna, and TOBI, the conspiracy claims relating to those drugs should be dismissed. The Court has squarely rejected that argument. *See United States ex rel. Kester v. Novartis Pharms. Corp.*, ___ F. Supp. 2d ___, 2014 WL 2619014, at *10 (S.D.N.Y. June 10, 2014) (*Novartis II*). Novartis also argues that Kester's conspiracy claims should be dismissed if its proposed causation standard is adopted. *Novartis II* is also dispositive of this argument, because the Court held in its decision that "[b]ecause conspiracy is an inchoate crime, the plaintiff need not prove that the defendant actually achieved the object of the conspiracy and completed a substantive FCA violation (such as the presentment of a false claim)." *Id*.

Novartis next argues that Kester lacks standing to assert any claim relating to Myfortic in which the United States has intervened. But while Novartis cavalierly claims that the law is "uniform" that a relator lacks standing in this context, the weight of judicial authority is actually the opposite. In addition, the plain language of the FCA demonstrates that Kester continues to have standing; it provides that after government intervention, the relator "shall have the right to continue as a party to the action," subject to limitations not at issue here. 31 U.S.C. § 3730(c)(1). Novartis's meritless standing argument should be rejected.

As to Kester's state FCA claims, Kester adopts the arguments of the Intervening States, which address most of the arguments raised by Novartis. Intervening State Br. at 12-17 (Dkt. No. 213). In response to Novartis's position that (some of) Kester's claims under the FCA of New Mexico may be barred on limitations grounds, that contention is wrong under New Mexico law, and Novartis's argument—which raises an affirmative defense—is not appropriate for a motion to dismiss. Kester's claims under the laws of Connecticut, Minnesota, Rhode Island, or Texas are also valid, although Kester does not seek retroactive application of those laws. However, retroactive application of Texas's FCA is appropriate if Texas subsequently intervenes

in this case.

ARGUMENTS & AUTHORITIES

I. Novartis's Proposed Causation Requirement is Unsupported in the Law

A. Novartis's Proposal Would Radically Narrow the Scope of the AKS and FCA

Novartis wrongly claims the FCA requires proof that (1) the drugs ordered as a result of the kickback were not medically necessary or appropriate, and (2) each kickback actually and improperly influenced the doctor or patient to prescribe or order the drugs at issue. Novartis Gov't Br. at 2-3, 16. As the Court observed in *Novartis I*, this unprecedented two-pronged requirement would dramatically narrow the FCA: "Such a rule would significantly restrict the definition of legally 'false' claims in the kickback context." *Novartis I*, at *25.

The FCA does not require the plaintiff to prove that a particular drug sale tainted by a kickback was not "medically necessary." It also does not require proof that each kickback had an improper influence on a doctor or patient. Novartis cannot point to a single case supporting either requirement. As the Court observed in *Novartis I*, the AKS does not require that a kickback actually succeed to establish a violation: "[I]t is the kickback arrangement itself that constitutes the AKS violation, not the success of the arrangement. The illegal recommendations in question do not have to actually convince someone to purchase the drugs who would not have otherwise done so." *Id.* at *19.

The nebulous question of whether a doctor or patient would have prescribed or taken medication in the absence of a kickback never has been relevant to the FCA either. Courts have routinely deemed kickback-tainted claims to be "legally false" on the theory of "false certification," where the claims were "affected by," "tainted by," or made "pursuant to" kickbacks. *New York v. Amgen, Inc.*, 652 F.3d 103, 113 (1st Cir. 2011) (under state Medicaid laws, question is whether claims were "affected by kickbacks"); *United States ex rel. Hutcheson*

v. Blackstone Med., Inc., 647 F.3d 377, 394 (1st Cir. 2011) ("If kickbacks affected the transaction underlying a claim, as Hutcheson alleges, the claim failed to meet a condition of payment."); *United States ex rel. Wilkins v. United Health Grp., Inc.,* 659 F.3d 295, 314 (3d Cir. 2011) (claims "tainted by" kickbacks are false); *United States ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 52 (D. Mass. 2011) ("claims for payment made pursuant to illegal kickbacks are false"). Here, that is true because all of the drugs included in the claims were sold to the pharmacies by Novartis pursuant to arrangements that included illegal kickbacks. Compl. ¶¶61-78. The caselaw—even the cases cited by Novartis—do not support either of the two prongs of Novartis's theory.

1. The Cases Do Not Require Plaintiff to Show Lack of "Medical Necessity"

Novartis cites a string of nine cases that, it claims, are "consistent with" Novartis's proposed "requirement of a causal link," Novartis Gov't Br. at 18, but that is untrue. For example, in *Hutcheson*, the plaintiff alleged that defendant "paid kickbacks to doctors across the country so they would use its products in certain spinal surgeries." 647 F.3d at 380. In rejecting the defendant's argument "that the physician claims nonetheless were not false or fraudulent because the claims were for services that would have been provided in the absence of the alleged AKS violations," *id.* at 393, the First Circuit declined to "cabin" the reach of the False Claims Act by requiring proof that services provided under a kickback arrangement were medically unnecessary, *id.* at 395.

In the remaining eight cases relied on by Novartis, the courts did not mention (much less require) either of Novartis's two pleading requirements: (1) that the items provided were not medically necessary or (2) that a kickback actually influenced the decision to order the item. Four of the eight cases Novartis cites are inapplicable, either because the facts alleged were so

vague that the complaints were dismissed under Rule 9(b),[1] or because the courts' decisions were based on an unrelated ground, like the statute of limitations.[2] The remaining cases did not apply Novartis's proposed requirements:

- In *United States ex rel. Kennedy v. Aventis Pharm., Inc.*, 610 F. Supp. 2d 938 (N.D. Ill. 2009), the court dismissed the claim because the relators had failed to point to any certification by a hospital that it had acted in compliance with the anti-kickback statute. *See id.* at 946. The court did not address the issue of causation.
- In *United States ex rel. Repko v. Guthrie Clinic, P.C.*, 557 F. Supp. 2d 522 (M.D. Pa. 2008), the court agreed that relator need not identify particular false claims because "every claim that was submitted to the government during the relevant time period was false because it was the result of referrals that were illegal." *Id.* at 527. The court did not address the issue of causation because that issue was irrelevant. *Id.* ("[T]he basis of the alleged fraud in each claim is the relationship between defendants, not anything unique to a particular claim, that has caused these claims to be allegedly fraudulent.").
- In the two *Pogue* cases, the relator conceded that the claims "were for necessary services rendered," and yet the courts denied the defendants' motions to dismiss, without requiring any allegation that the physicians' referral decisions would have been different

[1] *United States ex rel. Nunnally v. West Calcasieu Cameron Hosp.*, 519 Fed. Appx. 890, 894 (5th Cir. 2013) (the "complaint merely offers sweeping and conclusory allegations of 'verbal agreements' . . . without a shred of detail or particularity"); *United States ex rel. Moore v. GlaxoSmithKline, LLC*, 06 CIV. 6047 BMC, 2013 WL 6085125, at *5 (E.D.N.Y. Oct. 18, 2013) ("plaintiff has alleged neither available false claim with particularity"); *Hericks v. Lincare Inc.*, CIV.A. 07-387, 2014 WL 1225660, at *9 (E.D. Pa. Mar. 25, 2014) (as to first kickback allegation, plaintiff's "claims of kickbacks are rooted in conjecture, speculation, or supposition").

[2] *United States ex rel. Poteet v. Medtronic, Inc.*, 552 F.3d 503, 511 (6th Cir. 2009) ("Poteet's complaint is jurisdictionally barred by the public disclosure provision"); *Hericks*, 2014 WL 1225660, at *14 (plaintiff's other kickback claim is "barred by the statute of limitations").

"but for" the kickbacks. *United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am., Inc.*, 238 F. Supp. 2d 258, 261 (D.D.C. 2002); *accord United States ex rel. Pogue v. Am. Healthcorp Inc.*, 914 F. Supp. 1507, 1509 (M.D. Tenn. 1996) ("[T]he claims were not false in the sense that Defendants sought compensation for services that were not rendered or were unnecessary.").

Novartis's inability to find support for its novel causation requirement is hardly surprising. As Judge Easterbrook explained in *United States v. Rogan,* defendants cannot escape FCA liability by arguing that the services provided pursuant to kickbacks were nevertheless appropriate:

> Nor do we think it important that most of the patients for which claims were submitted received some medical care—perhaps all the care reflected in the claim forms . . . . When the conditions [of compliance with the AKS] are not satisfied, nothing is due. Thus the entire amount that [the hospital] received on these 1,812 claims must be paid back. Now it maybe that, if the patients had gone elsewhere, the United States would have paid for their care. Or perhaps the patients, or a private insurer, would have paid for care at Edgewater had it refrained from billing the United States. But neither possibility allows Rogan to keep money obtained from the Treasury by false pretenses, or avoid the penalty for deceit.

517 F.3d 449, 453 (7th Cir. 2008). The Second Circuit recently cited *Rogan*'s analysis on this point with approval (albeit in a non-kickback case). *United States ex rel. Feldman v. van Gorp*, 697 F.3d 78, 88 (2d Cir. 2012).

2. The Cases Do Not Require Physician Involvement

Similarly, Novartis's suggestion that the AKS requires proof of an "effect on a physician's treatment decision," Novartis Gov't Br. at 18 (emphasis added), is not supported by any case law. The AKS is not limited to doctors, or to prescription drugs. Although many AKS cases do involve allegations that physicians took or paid kickbacks, it does not follow that a physician's involvement is required. The statute's text says that "whoever" solicits or receives a kickback "shall be guilty of a felony," and the word "whoever" necessarily includes not only

doctors but also pharmacies, hospitals, nurses, caregivers, and anyone else who "recommend[s]" the "purchas[e]" of an "item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(1)(B).

Indeed, Novartis's argument has been squarely rejected by courts in criminal cases decided under the AKS, and courts have allowed FCA cases to proceed based on allegations of kickback transactions that did not involve physicians. *E.g.*, *McNutt ex rel. U.S. v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1258 (11th Cir. 2005) (affirming denial of a motion to dismiss where the defendant "medical services company" paid kickbacks to a "pharmacy" in exchange for referrals); *United States ex rel. Ruscher v. Omnicare, Inc.*, 4:08-CV-3396, 2014 WL 2618158 at *2-3 (S.D. Tex. June 12, 2014) (ruling that plaintiff stated a claim under the FCA based on allegations that the defendant pharmacy chain paid kickbacks to nursing homes in exchange for orders of pharmaceuticals and "pharmacist consulting, infusion and respiratory therapy, and medical supplies"); *United States ex rel. Lisitza v. Johnson & Johnson*, 765 F. Supp. 2d 112 (D. Mass. 2011) (same). As stated by the Eleventh Circuit: "the plain language of the [AKS] statute is not limited to payments to physicians who prescribe medication." *United States v. Vernon*, 723 F.3d 1234, 1253-54 (11th Cir. 2013) (emphasis added) (pharmacy CFO violated AKS by paying kickbacks to a non-physician for patient referrals); *see also United States v. Polin*, 194 F.3d 863, 866-867 (7th Cir. 1999) (pacemaker monitoring service employees violated AKS by paying kickbacks to pacemaker sales representative in exchange for his recommendations and referrals).

These cases are consistent with the longstanding guidance from the Department of Health and Human Servces ("HHS") that a pharmacist's receipt of kickbacks for promoting drugs violates the AKS. As Kester has previously observed, the HHS Office of Inspector General

("OIG") has long made clear that programs such as those conducted by Novartis and the specialty pharmacies are illegal. Payments by pharmaceutical companies to physicians and pharmacies violate the AKS if "one purpose of any of these marketing schemes is to induce the provision of a prescription drug reimbursable by Medicaid." Compl. ¶ 46 (citing OIG Special Fraud Alert, 94 Fed. Reg. 31,157 (Dec. 19, 1994)). The OIG further explained why these arrangements posed a public safety concern:

> Traditionally, physicians and pharmacists have been trusted to provide treatments and recommend products in the best interest of the patient. In an era of aggressive drug marketing, however, patients may now be using prescription drug items, unaware that their physician or pharmacist is being compensated for promoting the selection of a specific product.

Id. (emphasis added).

3. Novartis's Reading of the Law Would Radically Narrow the Scope of the Government Enforcement Efforts under the AKS and FCA

Novartis's proposed causation requirement, besides lacking caselaw support, would curtail the enforcement of these laws by introducing nebulous inquiries into the medical appropriateness of particular treatments and the decisionmaking processes of doctors and patients. Novartis Gov't Br. at 2 ("Accordingly, unless the Government alleges that a physician prescribed Myfortic based on an improper recommendation by a specialty pharmacy, or that a patient improperly ordered an Exjade refill because of communications with BioScrip, the claims for those prescriptions that it challenges should be not be deemed 'false claims' under the FCA."). These things have never before been FCA requirements, and for good reason. As indicated by the legislative history of the AKS, addressing a lack of medical necessity is not the purpose of the statute and, in any event, would be unduly difficult to prove if it were an element of culpability. H. Rep. No. 95-393 (1977), 1977 WL 16075, at *48 ("Furnishing excessive services is probably the most costly non-criminal abuse faced by health benefit programs. At the

same time, it is relatively difficult to prove and correct. Since the medical needs of a particular patient can be highly judgmental, it is difficult to identify program abuse as a practical manner unless the overutilization is grossly unreasonable.").

Novartis's view that imposing liability on them here would lead to "limitless liability" is unfounded. In this case, plaintiffs have alleged that all of the drugs included in the pharmacies' claims were obtained by the pharmacies from Novartis pursuant to arrangements in which the pharmacies agreed to accept illegal remuneration—whether inclusion in an exclusive drug distribution network, patient referrals, or kickbacks styled as "discounts" and "rebates." U.S. Amend. Compl. ¶161 (exclusive distribution network); Kester Compl. ¶¶57-61 (promise of future patient referrals); *id.* ¶¶62-64 (discounts and rebates). This distinguishes the instant case from one of the few cases Novartis cites to support its theory. *Kennedy*, 610 F. Supp. 2d at 946 (relator appeared to argue that all claims submitted by hospital were false, not just those limited to the drugs involved in the kickback arrangements).

4. Novartis's Citation to the Class-Action Certification Standard Is Irrelevant

Novartis argues that the Second Circuit's recent *Eli Lilly* decision nevertheless indicates that the Second Circuit would "require an allegation that an individual doctor 'relied on' the improper recommendations of pharmacists when writing a Myfortic prescription" before finding FCA liability based on an AKS violation. Novartis Gov't Br. 21 (citing *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 136 (2d Cir. 2010)). *Eli Lilly* is inapposite for a number of reasons. First, that case involved claims under RICO, not the AKS or FCA, for harm to third party payers that resulted from Eli Lilly's alleged false marketing of the drug Zyprexa to doctors. Unlike this case, the harm to be assessed was the monetary harm attributable to the plaintiff's coverage of medically unnecessary prescriptions. Here, the alleged harm is to Medicare, Medicaid and other government health programs, which are by health care providers who have abandoned their

obligations to deliver services free from the corruption of kickbacks. When a provider nonetheless bills the government for services tainted by kickbacks, it violates the conditions under which the Government has agreed to subsidize health care. Without any valid basis in the law, Novartis's argument denies the Government the right to refuse to subsidize health care in these circumstances.

B. The 2010 Amendment to the AKS Did Not Add a New Causation Requirement

As the Court observed in *Novartis I*, Novartis has seized on the phrase "resulting from" in a 2010 amendment to the AKS, contained in the Patient Protection and Affordable Health Care Act (PPACA), to support its novel causation requirement. However, as demonstrated below, neither the purpose, the legislative history, nor the text of the amendment supports Novartis's position.

1. Novartis Concedes That the 2010 Amendment "Did Not Add a New Causation Requirement"

Even Novartis does not dispute—and explicitly admits—that the 2010 amendment to the AKS "did not add a new causation requirement for an FCA action premised on a kickback claim." Novartis Gov't Br. at 9; *see also id.* at 13-14 ("As discussed above (supra at 9), the 2010 amendment was unrelated to the issue of causation . . . ."). This concession dooms Novartis's causation argument, because the law prior to the amendment clearly did not require the type of causation advocated by Novartis. Rather, claims submitted by parties in kickback relationships were considered "false" within the meaning of the FCA regardless of whether plaintiff could establish that the goods or services billed to the Government were medically unnecessary or that the person receiving the kickback actually offered biased advice as a result of the kickback.

2. Novartis's Reading Is Contrary to the Amendment's Purpose

Putting that concession to the side, on Novartis's flawed reading, an amendment designed to broaden the enforcement of the healthcare laws would end up accomplishing precisely the opposite—significantly narrowing the reach of the FCA. The amendment's purpose is reflected in its legislative history.

Statements by the bill's sponsors make clear that the Congress' intention was to clarify—and strengthen—the state of the law on the "implied false certification" doctrine: "By making all payments that stem from an illegal kickback subject to the False Claims Act, this bill leverages the private sector to help detect and recover money paid pursuant to these illegal practices." 155 Cong. Rec. S10852, 2009 WL 3460582, at *S10853 (daily ed. Oct. 28, 2009) (statement of Sen. Kaufman); *see id.* at S10854 (statement of Sen. Leahy) ("[The bill] would also amend the anti-kickback statute to ensure that all claims resulting from illegal kickbacks are considered false claims . . . .").[3]

According to the bill's sponsors, the purpose of the amendment was to reverse the outcome in *United States ex rel. Thomas v. Bailey*, No. 4:06-CV-00465, 2008 WL 4853630

[3] The 2010 amendment began in October 2009 as part of Senate Bill 1959: "A bill to improve health care fraud enforcement." S. 1959 § 2(b) (111th Cong., 1st Sess., 2009), *available at* http://www.gpo.gov/fdsys/pkg/BILLS-111s1959is/pdf/BILLS-111s1959is.pdf; *see* 155 Cong. Rec. S10852, 2009 WL 3460582, at * S10853 (daily ed. Oct. 28, 2009) (S. 1959 is introduced and referred to Committee on the Judiciary). The legislative history quoted is from the sponsors of S. 1959. After S. 1959 was introduced, it was immediately referred to the Committee on the Judiciary, where it died. *See* Library of Congress, THOMAS, S. 1959 Bill Summary and Status, http://thomas.loc.gov/cgi-bin/bdquery/z?d111:s.01959: (last viewed June 21, 2014).

Three weeks after S. 1959 was introduced, its AKS amendment was included, in modified form, in the omnibus health-care-reform bill introduced by Senator Harry Reid, which became the PPACA. S. Amend. 2786 to H.B. 3590, §6402(f) (111th Cong., 1st Sess., 2009), *reprinted in* 155 Cong. Rec. S11607-03, 2009 WL 3877374, at *11782 (Nov. 19, 2009); *see* John Cannan, *A Legislative History of the Affordable Care Act: How Legislative Procedure Shapes Legislative History*, 105 L. Lib. J. 131, 151 (2013) (describing background of Senate Amendment 2786).

(E.D. Ark. Nov. 6, 2008), a case in which the court had dismissed an FCA claim because the false claims had not been submitted by one of the parties to the kickback transaction, but rather had been submitted by the "innocent" hospital at which the physicians, who were paid kickbacks by the defendant manufacturer of spinal implants, had performed their surgeries. *See* 155 Cong. Rec. S10852, S10853 (daily ed. Oct. 28, 2009), 2009 WL 3460582 (Statement of Sen. Kaufman) ("This bill remedies the problem [caused by the *Bailey* holding] by amending the anti-kickback statute to ensure that all claims resulting from illegal kickbacks are 'false or fraudulent,' even when the claims are not submitted directly by the wrongdoers themselves."). Far from trying to confine the reach of the FCA in the AKS context, Congress sought to expand it. And notably, if Novartis's causation requirement had been applied in the *Bailey* case, the case would have been dismissed because the relator did not plead therein that the spinal implants or resulting back surgeries were medically unnecessary. Thus, Novartis's proposed causation requirement is contrary to Congress' own intentions in enacting the 2010 amendment.

3. Novartis's Causation Standard is Unsupported by the Text of the 2010 Amendment

Novartis's proposed causation requirement is also unsupported by the text of the 2010 amendment, which reads in relevant part: "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of the [FCA]." 42 U.S.C. § 1320a-7b(g). Novartis argues that the only way that plaintiffs can prove that the "items or services" "result[ed] from" an AKS violation is if they allege "that the pharmacies caused doctors to write . . . prescriptions that they otherwise would not have written, or caused patients to order . . . refills (in contravention of a doctor's instruction) that they otherwise would not have ordered." Novartis Gov't Br. at 14. Novartis's argument, however, is premised on several fundamental errors.

First, Novartis argues that the "items or services" referred to in the 2010 amendment are "prescriptions" for the drugs in question. *Id*. They are not. The claims that the pharmacies submitted to the government payors were not for a "doctor's prescription," but rather were for units of Myfortic, Gleevec, Tasigna, TOBI and Exjade. As alleged in the plaintiffs' complaints, the pharmacies had those drugs to distribute only by virtue of their arrangements with Novartis, the sole manufacturer of the drugs. And it was those arrangements that provided for the pharmacies to receive kickbacks for each pill that they obtained from Novartis. In this way, the "items or services" in question "resulted from" the alleged violation of the AKS. Novartis seeks to import other elements into the 2010 amendment that simply are not there. For instance, Novartis argues that the only way that the "items or services" could have "resulted from" a violation of the AKS is if a doctor wouldn't have prescribed a drug absent a recommendation from a pharmacy, or if a patient ordered a refill of a drug event though doing so was "in contravention of a doctor's instruction." Novartis Gov't Br. at 14. But that is ***not*** what the amendment requires. Novartis ignores the fact that a "violation of this section," i.e., the AKS, does not require that an illegal recommendation or solicitation be successful. Rather, Novartis "violates the AKS" the moment that it "offers" a kickback. *Novartis I*, at *19. "[I]t is the kickback arrangement itself that constitutes the AKS violation, not the success of the arrangement." *Id.* Plaintiffs have alleged that Novartis paid kickbacks to the pharmacies in exchange for each of the units of medication they dispensed (the "items or services" included in reimbursement claims). For that reason, each of the claims in question plainly included items—*i.e.,* the dispensed medication—that "result[ed] from" a violation of the AKS.

Finally, there is nothing in the use of the words "resulting from" that compels the radical narrowing of the law that Novartis suggests. The Supreme Court has made clear that terms like

"results from" can mean different things depending on the context of the statute in question, and that causation in general is a "flexible" concept. *See, e.g.*, *Paroline v. United States*, 134 S.Ct. 1710, 1727 (2014) (citing *Burrage v. United States*, 134 S. Ct. 881, 899-90 (2014), for the principle that "courts need not read phrases like 'results from' to require but-for causality where there is a 'textual or contextual' reason to conclude otherwise"); *id*. at 1719 (in interpreting criminal restitution statute using the terms "results in" and "proximate result," noting that "proximate cause" is a "flexible concept"). As stated by the Supreme Court in *Paroline*, when interpreting a causation standard in a remedial statute, a court "is required to define a causal standard that effects the statute's purposes." *Id*. at 1729. The Second Circuit has demonstrated similar flexibility in applying the words "resulting from" to the particular statutory context. *See United States v. Shellef*, 718 F.3d 94, 107 (2d Cir. 2013) (in "the context of [the Speedy Trial Act] as a whole," the words "resulting from" do not require "but for causation").

Such flexibility is especially important when interpreting the 2010 amendment. That amendment defined liability under the FCA, which is a "remedial statute." *United States v. Neifert-White Co.*, 390 U.S. 228, 233 (1968). It is a "familiar canon of statutory construction that remedial legislation should be construed broadly to effectuate its purposes." *Henrietta D. v. Bloomberg*, 331 F.3d 261, 279 (2d Cir. 2003) (relying on this canon to reject a "narrow[]" reading of a causation requirement in the Americans with Disabilities Act); *see Neifert-White Co.*, 390 U.S. at 233 (rejecting defendants' "narrow reading" of the FCA's term "claim" because Congress's remedial goal "was broadly to protect the funds and property of the Government"). Novartis's narrow reading of this statute, which plainly conflicts with the FCA's remedial purpose, should be rejected "if alternative interpretations consistent with the legislative purpose

are available," which they plainly are. *Phillips v. Saratoga Harness Racing, Inc.*, 240 F.3d 174, 179 (2d Cir. 2001) (quoting *Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 575 (1982)).

As set forth above, Novartis paid kickbacks to the specialty pharmacies for all of the drugs that were included in the pharmacies' claims for reimbursement. Every claim submitted in this case therefore "result[ed] from" the "kickback arrangement" between Novartis and the specialty pharmacies.

II. Kester's Conspiracy Claims Should Not Be Dismissed

Novartis also contends that Kester's conspiracy claims should be dismissed. First, Novartis argues that dismissal of the claims relating to Gleevec, Tasigna and TOBI is warranted on the ground that Kester failed to identify with the particularity required by Rule 9(b) the "false claims" that were the goal of the conspiracy. That argument is procedurally and substantively improper.

As a threshold matter, Novartis improperly reargues a point that this Court already decided in *Novartis II*, which is that Kester need not plead false claims with particularity for purposes of its claims under the "conspiracy" liability provision in the FCA and the analogous state laws under which Kester sues. *See Novartis* II, at *10. Putting aside the fact that this is a Rule 9(b) argument that Novartis did not receive permission to file at this juncture, Novartis violated Local Rule 6.3 by failing to present this argument in a separate motion for reconsideration "setting forth concisely the matters or controlling decisions which counsel believes the Court has overlooked." (Emphasis added.)

In any event, Novartis's argument is meritless: Kester's conspiracy claims do not require particularized details (the "who, what, when, where, how") of the false claims themselves. That is because, as this Court also correctly held, "no false claim need have been submitted for subsection (a)(l)(C) liability to attach." *Novartis II*, at 18. Novartis explicitly admits this fact, at

least with respect to the post-2009 version of the statute. Novartis Kester Br. at 5 (conceding that "a civil conspiracy under the post-2009 FCA does not require the submission of a false claim"). This was also the law under the pre-2009 version of the FCA, as confirmed by the leading authority cited by the Court: *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 193 (5th Cir. 2009) ("[P]resentment of a false claim need not be proven nor pled to prevail on a False Claims Act conspiracy charge."); *see also United States v. St. Luke's Subacute Hospital & Nursing Centre, Inc.*, 2004 WL 2905237, *5 (N.D. Cal. Dec. 16, 2004) ("[P]roof that a false claim was actually presented to or paid by the government as a result of the conspiracy is not necessary for a defendant to be held liable . . . under [FCA] § 3729[a](3)." (quoting *Blusal Meats, Inc. v. United States*, 638 F. Supp. 824, 828 (S.D.N.Y. 1986)). Novartis ignores these decisions in its brief, and plainly does not present any "controlling decision" which would require the Court to reverse its prior ruling.

The same logic applies to Novartis's argument that plaintiffs' conspiracy claims should be dismissed if its proposed causation standard, addressed *supra* in Part I, is adopted. Whether or not the current complaints plead the type of causal link that Novartis wrongly suggests is necessary in this context, there is no question that the complaint alleges the existence of an unlawful agreement to influence patients and physicians to order the drugs in question through the payment of kickbacks. That was an object of the kickback arrangements, as Novartis itself observes in describing the Government's complaint. *See, e.g.,* Novarts Gov't Br. at 5 (kickbacks as to Exjade alleged to be paid "to BioScrip in exchange for which BioScrip promoted Exjade by engaging in 'intensive' adherence-related efforts"); Kester Compl. ¶29 (Novartis's purpose was to "increase sales of of certain specialty medications"). Novartis's argument is, once again, simply that the complaint does not allege the presentment of actual claims resulting from that

conspiracy, which is not an element of a conspiracy claim, as this Court has already concluded in *Novartis II*.

III. Kester Still Has Standing, So His Myfortic Claims Should Not Be Dismissed

Novartis argues that because Kester's Myfortic claims are "duplicative" of the United States' Myfortic claims, he "lacks standing" and therefore his federal Myfortic claims should be "dismissed." Novartis Kester Br. at 6-7. Novartis concedes that Kester's state Myfortic claims remain in the case. *Id.* at 7. In support of its argument, Novartis asserts that "Courts in this District and throughout the country have uniformly held that a relator lacks standing to pursue claims that are duplicative of the ones the United States asserts in intervention." *Id.*at 6.

Novartis is wrong. In fact, courts have rejected similar arguments raised by defendants in other cases. *See, e.g.*, *United States ex rel. Landis v. Tailwind Sports Corp.*, 2014 WL 2772907, *7 (D.D.C. June 19, 2014) (ruling that defendant's contention that relator lacks standing following government's intervention has "no merit" because "[n]othing in the text of section 3730 indicates that a relator no longer has standing following intervention by the Attorney General"); *United States ex rel. Wilkins v. North Am. Construction*, 173 F. Supp. 2d 601, 645 (S.D. Tex. 2001) (denying motion to dismiss relator's complaint after government intervened) ; *cf. United States ex rel. Long v. SCS Bus. & Technical Inst, Inc.*, 173 F.3d 870, 885 (D.C. Cir. 1999) (for state sovereign immunity purposes, "[w]e simply do not see how the government's potential exercise of its power [to intervene] renders the relator any less a party").

More importantly, the plain language of the statute supports Kester's argument: Section 3730(c)(1) provides that, after government intervention, "[the relator] shall have the right to continue as a party to the action, subject to the limitations set forth in paragraph (2)." Paragraph (2), in turn, sets forth mechanisms by which the government may limit the relator's role, if the government chooses to do so. (The government has not done so in this case.) The defendant, on

the other hand, may ask the court to limit the relator's role only upon a showing "that unrestricted participation during the course of the litigation by the person initiating the action would be for purposes of harassment or would cause the defendant undue burden or unnecessary expense." 31 U.S.C. § 3730(c)(2)(D). Novartis has not even attempted to meet that standard.

Three of the cases Novartis cites in support of its position actually are consistent with Kester's view—or at the very least unclear as to what relief the courts are granting. In *United States ex rel. Allen v. Guidant Corp.*, CIV. 11-22 DWF/AJB, 2012 WL 878023 (D. Minn. Mar. 14, 2012), the court denied the defense's motion to dismiss the relator's complaint, on the ground that the government had only "partially intervened," as the government has also done in the present case. *Id.* at *6. In three other cases, the court granted the motion to dismiss but noted that "Relator remains a party to these claims and is entitled to participate pursuant to the statute." *United States ex rel. Robinson-Hill v. Nurses' Registry & Home Health Corp.*, CIV.A. 5:08-145-KKC, 2012 WL 4598699, at *9 (E.D. Ky. Oct. 2, 2012); *United States ex rel. Magee v. Lockheed Martin Corp.*, CIV. 109CV324HSOJMR, 2010 WL 972214 (S.D. Miss. Mar. 12, 2010) (same).

It is unclear what effect a dismissal accompanied by "participation" would have—except to permit Novartis to litigate whether Kester's continued involvement in his case is within the statute's limits and perhaps to provide Novartis with an opportunity to improperly argue down the road that Kester should be denied a share in any recovery by the federal Government. Such a result plainly would be an unjust consequence, especially where it was Kester's information that led to the Government's investigation of and intervention in the Myfortic claims, and no defendant has even tried to argue to the contrary. Novartis' motion is an attempted "end-run" around the criteria that must be met before a relator may be denied the statutory right to

participate in the litigation of his claims or the right to recover a relator share based on such claims.

Only two cases advance the position advocated by Novartis. The first, *United States ex rel. Feldman v. City of New York*, 808 F. Supp. 2d 641, 649 (S.D.N.Y. 2011), does not cite authority for its "standing" analysis, and the other case cites *Feldman* with no further analysis, in what may be dicta given the dismissal of all of the government's claims under separate grounds. *United States ex rel. Badr v. Triple Canopy, Inc.*, 950 F. Supp. 2d 888, 895 n.1 (E.D. Va. 2013).[4] This Court should not follow *Feldman* in this case. Novartis makes no effort to square *Feldman*'s "standing" argument with the Supreme Court's definitive opinion on the subject: "[T]he United States' injury in fact suffices to confer standing on [the relator]." *Vermont Agency of Natural Resources v. United States ex rel. Stevens*, 529 U.S. 765, 774 (2000). Nothing in the *Stevens* Court's opinion suggests that the relator loses standing when the government intervenes. To the contrary, consistent with the text of the statute, the *Stevens* Court recognized and affirmed that the FCA "gives the relator 'the right to continue as a party to the action' even after the Government has intervened." *Id.* "Nothing in the [*Stevens*] opinion suggests that the government and defendants can eliminate the relator's participation in the lawsuit except under the circumstances set forth in the statute." *Wilkins,* 173 F. Supp. 2d at 645 (denying motion to dismiss relator's complaint after government intervened). If Novartis wishes to "limit" Kester's "participation," it must first to convince the Court that Kester's "unrestricted participation during the course of the litigation . . . would be for purposes of harassment or would cause the defendant

[4] Importantly, even *Feldman* made clear that regardless of the relator's standing to assert the claims in question, the relator's statutory rights would be preserved. *Feldman*, 808 F. Supp. 2d at 649 (dismissal "in no way diminishes Feldman's continuing statutory rights").

undue burden or unnecessary expense." 31 U.S.C. § 3730(c)(2)(D). Novartis has not even attempted to make this showing.

IV. Kester's State False Claims Act Claims Are Valid

As to Novartis's arguments regarding the FCAs of Intervened States (Georgia, Maryland, New Jersey, New York, Oklahoma, and Wisconsin), Kester herein incorporates by reference the arguments made by those states as to the retroactivity of their laws, which arguments confirm that Kester's state FCA claims are valid for the entire period under Maryland, New York, and Wisconsin law.

With regard to the statute of limitations argument that Novartis makes with regard to the false claims law of New Mexico, a state that has not intervened herein, Novartis is wrong that New Mexico's four-year statute of limitations bars Kester's claims that arise before November 14, 2007, because this statute of limitations is subject to a discovery rule, permitting Kester to sue within four years of his discovery of the fraud. Not until much later did Kester have "discovery of such facts as would, on reasonable diligent investigation, lead to knowledge of fraud or other injury." *Wilde v. Westland Dev. Co., Inc.*, 241 P.3d 628, 635 (N.M. 2010). Further, whether this discovery rule triggered the statute of limitations is a question that is not properly decided upon a motion to dismiss. *In re S. African Apartheid Litig.*, 617 F. Supp. 2d 228, 287 (S.D.N.Y. 2009) ("[A] court must deny a motion to dismiss based on the statute of limitations "unless 'all assertions of the complaint, as read with required liberality, would not permit the plaintiffs to prove that this statute was tolled.'").[5]

[5] Kester does not seek retroactive application of the FCAs of Connecticut, Minnesota, or Rhode Island, and he agrees that his recovery under the Texas FCA must be based on conduct occurring after May 4, 2007. However, if Texas later intervenes in this case, then Texas will be authorized to seek recovery based on conduct occurring prior to that date.

V. Kester Adopts the United States's Arguments on Legal Falsity

In its motion to dismiss Kester's complaint, Novartis does not make an argument related to the doctrine of legal falsity, aside from the 2010 amendment. However, Novartis appears to raise the issue in a footnote to the separate motion to dismiss the United States's complaint-in-intervention. Novartis Gov't Br. at 15 n.3. Kester incorporates herein the responses of the United States in opposition to that motion, and also the arguments made in pages 17 to 22 of his Memorandum in Opposition to the Pharmacy Defendants' Motions to Dismiss, Docket No. 187.

Notably, Novartis does not address whether, aside from legal falsity arising from the text of the AKS, falsity may be established based on the certifications or representations made by the pharmacies, including but not limited to the pharmacies' representations of AKS compliance in Medicaid provider agreements, Medicare Part B enrollment agreements, *see* Compl. ¶51, and Medicare Part D contracts with Part D sponsors. As to Part D, Kester observes that the regulations governing Medicare Part D require that pharmacies billing Part D enter into contracts with sponsors in which they agree to "comply with the Medicare Part D sponsor's contractual obligations" when providing services, 42 C.F.R. 423.505(i)(3)(iii), which include compliance with "Federal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to applicable provisions of Federal criminal law, the False Claims Act . . . and the anti-kickback statute." *Id*. (h)(1) (setting forth requirements for sponsors' annual contracts). When a pharmacy nonetheless bills Medicare Part D for drugs tainted by kickbacks, it violates its contracts with the Part D sponsors, causing the sponsors to submit false claims to Medicare Part D. Violation of these conditions in the pharmacies' contracts is one of the grounds for falsity alleged in the Relator's complaint. *See, e.g.*, Kester Compl. ¶29 ("Novartis entered into the kickback arrangements alleged herein while knowing that these kickbacks were prohibited by federal and state law, regulation, policy and contract condition" and "Novartis knew that federal

and state governments required, as a condition of paying any such claim for reimbursement, that the pharmacies not have violated any federal or state laws, regulations, or contract conditions that forbade them from accepting kickbacks" (emphasis added)); *id.* ¶79 (incorporating Government's allegations concerning Exjade); U.S. Amend. Compl. ¶228 (BioScrip "promised to comply" with the AKS "in its contracts with Part D sponsors").

CONCLUSION

For the foregoing reasons, Kester respectfully submits that the motion to dismiss filed by defendant Novartis should be denied.

Respectfully submitted,

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